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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,418	11/16/2000	David A. Lewin	10716/12	7715

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/715,418	LEWIN ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- Th MAILING DATE of this communicati n appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed July 24, 2003 has been entered. Claims 42-65 are pending and being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC §§ 101, 112

Claims 42-65 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant argues that SEQ ID NO: 3 was identified in a model for cancer (Tsukamoto et al., 1988; Wong et al., 1994). Applicant's arguments have been fully considered but they are not persuasive. Tsukamoto et al. (1988) and Wong et al. (1994) are not of record in the present application and the examiner cannot comment on evidence that is not of record.

Applicant argues that SEQ ID NO: 3 was shown to be upregulated in tumor cells. Applicant's arguments have been fully considered but they are not persuasive. There is no objective evidence of record that supports this assertion.

Applicant argues that expression of SEQ ID NO: 3, as evidenced by its human homolog, is restricted to a few tissues. Applicant's arguments have been fully considered but they are not persuasive. While this may be true for the human homolog SEQ ID NO: 5, the present specification provides no information regarding level of expression, activity, or role in cancer of SEQ ID NO: 3.

Applicant argues that SEQ ID NO: 3, as evidenced by its human homolog, is up-regulated in colon, breast, and ovarian cancer cells but not in the tested wild-type tissues. While

this may be true for the human homolog SEQ ID NO: 5, the present specification provides no information regarding level of expression, activity, or role in cancer of SEQ ID NO: 3. Furthermore, Table 8 in the present specification shows that the expression of SEQ ID NO: 5 can be either up-regulated, down-regulated, or unchanged in colon, breast, and ovarian cancer cells with respect to the normal tissue counterparts. It is clear from Table 8 that one would not know whether the expression of SEQ ID NO: 3 or SEQ ID NO: 5 should be up-regulated, down-regulated, or unchanged in a particular cancer.

Applicant argues that antibodies against SEQ ID NO: 3 can be used to detect colon, breast, and ovarian cancer cells. While this may be true for the human homolog SEQ ID NO: 5, the present specification provides no information regarding level of expression, activity, or role in cancer of SEQ ID NO: 3. It is entirely unclear why one would use antibodies to a polypeptide (SEQ ID NO: 3) less than identical to a polypeptide (SEQ ID NO: 5) to detect diseases in which SEQ ID NO: 5 may be involved, when one could use antibodies to the identical polypeptide (SEQ ID NO: 5).

Applicant argues that the detection or treatment of ovarian cancer is a substantial utility. Applicant's arguments have been fully considered but they are not persuasive. Table 8 in the present specification shows that the expression of SEQ ID NO: 5 can be either up-regulated, down-regulated, or unchanged in colon, breast, and ovarian cancer cells with respect to the normal tissue counterparts. It is clear from Table 8 that one would not know whether the expression of SEQ ID NO: 3 or SEQ ID NO: 5 should be up-regulated, down-regulated, or unchanged in a particular cancer. Further experimentation would be required in order to identify or reasonably confirm the detection or treatment of ovarian cancer with SEQ ID NO: 3. Utilities

that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Claims 42-65 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments have been fully considered but they are not persuasive. A rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it. As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection set out a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. A 35 U.S.C. 112, first paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

Claims 42-61, 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that this rejection has been obviated by amendment. Specifically, Applicant is specifically claiming SEQ ID NO: 3 and the added functional limitations further obviate the rejections. The human sequence (SEQ ID NO: 6) provides guidance for modifying the mouse sequence (SEQ ID NO: 3). Applicant's arguments have been fully considered but they are not persuasive.

The claims are directed to or encompass a polypeptide comprising an amino acid sequence having at least 90, 95, or 99% identical to the SEQ ID NO: 3 or a polypeptide comprising at least 10 amino acids of SEQ ID NO: 3. The claims further require that the polypeptide binds an antibody that selectively binds a polypeptide of SEQ ID NO: 3. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof that fully set forth the claimed invention. It is noted that SEQ ID NO: 3 is a partial, i.e., less than full-length, polypeptide because the initiator methionine is missing. Yet the claims encompass a full length polypeptide. Applicant's were not in possession of the full-length polypeptide. The property of binding an antibody says nothing regarding the function of the polypeptide other than it binds the antibody. The claims do not require that the polypeptide bind any particular antibody that binds any particular epitope.

Furthermore, there is no disclosed correlation between the structure implied by the binding of any particular antibody and the function of the polypeptide. Therefore, the recitation of "binds an antibody that selectively binds ... SEQ ID NO: 3" does not fully set forth the claimed invention.

The claims are directed to or encompass a polypeptide consisting of an amino acid sequence 90, 95, 99% identical to SEQ ID NO: 3. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by some level of sequence identity. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof that fully set forth the claimed invention. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claims 42-61, 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that this rejection has been obviated by amendment. Specifically, Applicant is specifically claiming SEQ ID NO: 3 and the added functional limitations further obviate the rejections. The human sequence (SEQ ID NO: 6) provides guidance for modifying the mouse sequence (SEQ ID NO: 3). Applicant's arguments have been fully considered but they are not persuasive.

The claims are directed to or encompass a polypeptide comprising an amino acid sequence having at least 90, 95, or 99% identical to the SEQ ID NO: 3 or a polypeptide comprising at least 10 amino acids of SEQ ID NO: 3. The claims further require that the polypeptide binds an antibody that selectively binds a polypeptide of SEQ ID NO: 3. The property of binding an antibody says nothing regarding the function of the polypeptide other than it binds the antibody. The claims do not require that the polypeptide bind any particular antibody that binds any particular epitope. Furthermore, there is no disclosed correlation between the structure implied by the binding of any particular antibody and a particular function of the polypeptide. Therefore, the recitation of "binds an antibody that selectively binds ... SEQ ID NO: 3" does not enable the skilled artisan to use the full scope of the claimed invention.

The claims are directed to or encompass a polypeptide consisting of an amino acid sequence 90, 95, 99% identical to SEQ ID NO: 3. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by some level of sequence identity. The claim encompasses an unreasonable

number of inoperative polypeptides, which the skilled artisan would not know how to use. The skilled artisan would not know how to use non-identical polypeptides unless they possessed the function of the identical polypeptide.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 42-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 42-57 are indefinite because they recite the term "selectively binds." Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "selectively binds" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46, 47, 49, 54, 55, 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandman (A) (U. S. Patent No. 6,117,989). Bandman discloses a purified CaBP polypeptide

(column 3, full paragraph 2; column 5, full paragraph 2; paragraph bridging columns 13-14), wherein the polypeptide is further fused to a heterologous polypeptide (column 17, full paragraph 2), and compositions comprising the polypeptide and a carrier (column 4, full paragraph 2). CaBP comprises or consist essentially of a fragment of at least 10 amino acids of the present application's SEQ ID NO: 3, as indicated below:

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US-09-048-889-5
; Sequence 5, Application US/09048889
; Patent No. 6117989

Qy      28 MGQCRSANAEDAQEFSDVERAIETLIKNFH 57 (SEQ ID NO: 3)
           ||||||||||||||||||||||||||||||
Db       1 MGQCRSANAEDAQEFSDVERAIETLIKNFH 30 (CaBP).
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Although Bandman is silent with respect to CaBP binding "an antibody that selectively binds ... SEQ ID NO: 3," when the claimed and prior art products are identical or substantially identical in structure or composition claimed properties or functions are presumed to be inherent, and a prima facie case of either anticipation or obviousness has been established. Applicant has the burden of distinguishing between CaBP and the claimed peptide.

Drawings

Although Applicant indicates that replacement sheets for the drawings were submitted, either these sheets were not submitted or they have been misplaced and they are not of record in the present application.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
NOVEMBER 21, 2003